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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,711	02/17/2006	Hidenori Urata	Q93208	4660

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
11/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@SUGHRUE.COM
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Office Action Summary	Application No.	Applicant(s)	
	10/568,711	URATA ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 40-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 pages (05/21/2009, 08/27/2009 and 09/21/2009)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of t/e previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/27/2009 has been entered.

Status of Application

2. The Examiner acknowledges receipt of the amendments filed on 08/27/2009 wherein claims 40-43 are newly added.

3. Claims 1, 2 and 40-43 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 08/27/0009 regarding the rejection of claims 1 and 2 made by the Examiner under 35 USC 103(a) over Nishimura et al. (US 6410576) in view of Tsuchiya et al. (EP 1249450), Iimura et al. (AJH, 1995), Ishihara et al. (WO 01/12226) and Nishimura et al. (WO 01/32621) have been fully considered but they are not found persuasive.

5. The rejection of claims 1 and 2 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 02/27/2009.

6. In regards to the 103(a) rejection, Applicant asserts the following:

A) The thiazolidine compounds of Nishimura treat complications of diabetes by exerting PPAR-gamma agonistic activity and not because of chymase inhibitory activity; and

B) None of the secondary teachings provide evidence that chymase inhibitors improve glucose intolerance or are useful for treating diabetes.

7. In response to A, this argument is not found persuasive. Nishimura states at column 10 that, "Chymase has been reported to participate also in outbreaks of cardiac infarction, heart failure, blood-vessel restenosis after PTCA and the like (Blood Vessel & Endothelium,5 (5), 37 (1995)), hypertension (FEBS Lett., 406, 301(1997)), diabetes complication (Biol. Chem., Hoppe Seyler (GERMANY, WEST), 369 Suppl., p299), allergic diseases (Nobuhiko Katsunuma, "Intracellular Proteolysis", p. 101-106), asthma (J. Pharmacol. Exp. Ther., 244 (1), 133 (1987)) and the like. Chymase inhibitors are expected to be effective in treating these diseases." In fact, it is unclear to the Examiner how exactly Applicant arrived at the compounds exhibiting PPAR activity because nowhere in the reference of Nishimura is PPAR activity discussed.

8. In response to B, this argument is not persuasive either. As Nishimura teaches that chymase inhibitors are useful for treating diabetic complications, any ordinary person could have identified and implemented the chymase inhibitors as taught by Tsuchiya, i.e. 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid, with a reasonable expectation for success in treating said complications. Tsuchiya does not have to disclose that said compound is useful for treating diabetes and its complications because Nishimura teaches that chymase inhibitors provide such a benefit. Moreover, as a complication of diabetes includes impaired glucose tolerance, it would readily occur to a person of ordinary skill that by treating diabetes with or without a chymase inhibitor would necessarily treat the patients ability to tolerate blood glucose. Treating the disease (diabetes) would necessarily treat the symptom (glucose intolerance).

Maintained Rejections, of Record (claims 1 and 2) and New Rejections, Necessitated by Amendment (claims 40-43)
Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. **Claims 1, 2 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (US Patent 6,410,576; of record) in view of all Tsuchiya et al. (EP 1249450; of record), Iimura et al. (AJH, 1995, 8, 353-357; of record), Ishihara et al. (WIPO Document WO01/1222; of record) and Nishimura et al. (WIPO Document WO 01/32621; of record, hereinafter Nishimura1).**

11. Nishimura teaches that compounds that exhibit chymase inhibitory activity are expected to be effective at treating diabetes complications (see columns 9, line 62 to column 10, line 17). Chymase inhibitor compounds are expected to be useful as drugs, particularly to be effective in treating various diseases originating from chymase such as diabetes complications (see column 52, lines 17-22).

12. Nishimura does not teach the specific diabetes complications or the underlying mechanism creating the complications. In addition, Nishimura does not identify 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid as a chymase inhibitor.

13. Tsuchiya teach benzimidizole derivatives as an inhibiting agent against human chymase activity is clinically applicable as a treating agent for various diseases associated with human chymase (see page 2, paragraphs 1 and 7 and page 67, paragraph 238). Tsuchiya et al. teach that

the benzimidizole derivatives have an extremely high chymase inhibitor activity and that one such disclosed derivative is 4-(1-((4 methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid (page 2, paragraph 5 and Page 8, compound 56 and Example 15, page 64).

14. Iimura teach an ACE inhibitor improves insulin-resistant glucose uptake (insulin sensitivity) in the insulin-resistant hypertensive rat model and essential hypertensives (see abstract).

15. Ishihara teach that compounds having a chymase inhibitory effect are expected to be a treatment of diseases such as diabetic retinopathy (see abstract).

16. Nishimura1 teaches chymase compounds that exhibit excellent inhibitory activity are useful as therapeutic drugs to treat complications of diabetes and obesity (see abstract).

17. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, that if chymase inhibitors in general were effective at treating complications of diabetes as disclosed by Nishimura and one had a compound such as 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid which is taught by Tsuchiya as having extremely high chymase inhibitor activity, the compound taught by Tsuchiya would also treat diabetes complications such as glucose intolerance. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention, that in treating the complications associated with diabetes, one would also inherently treat the underlying cause of diabetes which would be the insulin resistance and associated glucose intolerance. See MPEP 2112.01 II, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are

necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), and, as such, it would be expected that a compound that treated diabetes complications would have to treat the underlying cause of diabetes, like glucose intolerance. Therefore, absent evidence to the contrary from Applicant, the method taught by Nishimura in view of Tsuchiya and that disclosed by Applicant will possess the same effect since identical products cannot have mutually exclusive properties. The inclusion of an ACE inhibitor along with the chymase inhibitor would also be obvious because it is *prima facie* obvious to combine two compositions, both of which are known to be useful for the very same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
October 28, 2009

/David J Blanchard/
Primary Examiner, Art Unit 1643